

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)))))	MDL NO. 1203
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THIS DOCUMENT RELATES TO:)))	
SHEILA BROWN, et al.)))	CIVIL ACTION NO. 99-20593
v.)))	
AMERICAN HOME PRODUCTS CORPORATION)))	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8930

Bartle, J.

August 28, 2012

Elaine P. Tassinari ("Ms. Tassinari" or "claimant"), a class member under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Frederick J. Tassinari, Ms. Tassinari's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In June, 2006, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Andrew J. Kemper, M.D. Based on an echocardiogram dated July 6, 2007, Dr. Kemper attested in Part II of Ms. Tassinari's Green Form that she suffered from severe mitral regurgitation and chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation⁴.

3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, the presence of chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation, requires
(continued...)

Dr. Kemper also attested that claimant had surgery to repair or replace the aortic and/or mitral valve(s) after use of Pondimin® and/or Redux™ and suffered a stroke due to (a) bacterial endocarditis contracted after use of Pondimin® and/or Redux™, or (b) chronic atrial fibrillation with left atrial enlargement as defined in Green Form Question F.5., or (c) valvular repair and/or replacement surgery which resulted in a permanent condition which meets the criteria for Functional Level III of the AHA Stroke Outcome Classification System, determined six months or later after the event.⁵ Based on such findings, claimant would be entitled to Matrix B-1, Level IV benefits in the amount of \$91,665.⁶

In January 2009, the Trust forwarded the claim for review by Craig M. Oliner, M.D., one of its auditing cardiologists. Although Dr. Oliner concluded that there was no

4. (...continued)
the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c).

5. Dr. Kemper also attested that claimant had an abnormal left ventricular dimension; an abnormal left atrial dimension; arrhythmias; a reduced ejection fraction in the range of 50% to 60%; and valvular repair or replacement surgery requiring a second surgery through the sternum within 18 months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery. These conditions are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level IV benefits if he or she suffers a stroke caused by aortic and/or mitral valve surgery when the stroke has produced a permanent condition that meets the criteria of AHA Stroke Outcome Classification Functional Levels II or III determined six months after the event. See Settlement Agreement § IV.B.2.c.(4)(e).

reasonable medical basis for Dr. Kemper's finding that claimant had a stroke resulting in a permanent condition which meets the criteria for Functional Level III of the AHA Stroke Outcome Classification System, determined six months or later after the event, he did determine there was a reasonable medical basis for the attesting physician's finding that Ms. Tassinari had mitral valve replacement surgery.

Based on Dr. Oliner's findings, the Trust issued a post-audit determination that Ms. Tassinari was entitled only to Matrix B-1,⁷ Level III⁸ benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁹ In support, claimant

7. In addition to the attesting physician's representation that claimant had chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation, the Trust determined claimant was entitled to the payment of reduced Matrix Benefits because Dr. Oliner concluded her December 14, 2002 echocardiogram, which was performed between the commencement of Diet Drug use and the end of the Screening Period, demonstrated mild mitral regurgitation. See Settlement Agreement § IV.B.2.d.(2)(a). Further, the Trust determined that the length of claimant's Diet Drug usage was 60 days or less, which also would require the payment of reduced Matrix Benefits. Id. § IV.B.2.d.(2)(b). Claimant filed an untimely appeal to arbitration with respect to this determination. Given our disposition, we will dismiss her appeal as moot.

8. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition
(continued...)

submitted a May 29, 2009 letter from Andrew H. Leader-Cramer, M.D., in which he stated, in relevant part:

In my opinion, and to a reasonable degree of medical certainty, I would consider that your status at this time is a Functional Level III in view of your significant visual impairment, together with visual spatial difficulties, difficulty in balance and ongoing sensory and motor disturbance in your right upper extremity due to your brachial plexus neuropathy which was also the result of the cardiac surgery that you sustained.

In addition, claimant submitted a December 15, 2008 letter from her attesting physician, which stated, in relevant part, the following:

Mrs. Tassinari suffered a stroke at the time of her surgery for mitral regurgitation. At this point, she has problems with short-term memory, is unable to handle her finances, cash, or appointments and relies entirely on her husband. She is unable to drive a car or find her way to places that she has been before. She has frequent problems with short-term memory.

She also has problems with her vision and persistent weakness and pain in her right arm, is unable to open jars, bottles, or cans, cannot read a book. The problems with her vision appear to be central.

I believe that, by the stroke classification level, she would be considered to be functional level III with three neurological domains impaired and a moderate deficit due to the stroke in all three domains.

9. (...continued)

of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Tassinari's claim.

(Emphasis in original).

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Oliner submitted a declaration in which he found that there was a reasonable medical basis to find that claimant suffered a stroke due to valvular replacement surgery and that claimant's stroke resulted in a permanent condition meeting the criteria for Functional Level II of the AHA Stroke Outcome Classification System.

The Trust then issued an amended post-audit determination that claimant was entitled to Level IV benefits. The Trust, however, again determined that Ms. Tassinari was entitled only to Matrix B benefits based on the presence of three reduction factors, namely, the presence of chordae tendinae rupture, the presence mild mitral regurgitation demonstrated by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, and the usage of Diet Drugs for 60 days or less. Claimant disputed this amended post-audit determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Tassinari's claim should be paid. On October 27, 2009, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8332 (Oct. 27, 2009).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on July 6, 2010, and claimant submitted a sur-reply on September 28, 2010. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis supporting her claim for Matrix A-1, Level IV benefits. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant asserts that she should receive Matrix A benefits because her physical condition has worsened over the years following her use of Diet Drugs and her current physical ailments were "reasonable complications of [her] original surgery." Claimant also argues that her claim should not be reduced because her medical records reflect that she does not have chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute

mitral regurgitation.¹⁰ Finally, claimant asserts that the auditing cardiologist improperly "ignored" the reports of her physicians.¹¹

The Trust counters that claimant has not adequately rebutted the presence of chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation, which, under the Settlement Agreement, reduces a mitral valve claim to the B Matrix. The Trust also argues that, to establish her eligibility, claimant relied on her December 14, 2002 echocardiogram, which stated that claimant only had mild mitral regurgitation. Accordingly, the presence of mild mitral regurgitation between Diet Drug use and the close of the Screening Period also requires claimant's Level IV claim to be paid on the B Matrix.

10. In addition, Ms. Tassinari contends that her husband is entitled to derivative benefits. Although the Trust concedes Mr. Tassinari is entitled to derivative benefits, it does not appear he has been paid. While any payment to Ms. Tassinari is subject to the procedures governing Medicare liens set forth in Court-Approved Procedure No. 10, which was approved by this court in PTO No. 6085 (Mar. 29, 2006), any payment to Mr. Tassinari is not and should be processed independent of the resolution of Ms. Tassinari's Medicare lien.

11. Claimant also challenges the Trust's determination as to the amount of her Matrix Benefits. Specifically, claimant argues that the Trust should have based her benefit amount on her age at the time of her Diet Drug use. As noted by the Trust, the Settlement Agreement states that the amount of Matrix Benefits is determined by "the age at which the Diet Drug Recipient is first diagnosed as suffering from that level of disease severity." Settlement Agreement § IV.B.2.b. As nothing in the Show Cause Record reflects any error by the Trust in calculating the claimant's age at the time of diagnosis of her Level IV condition, the court rejects this argument.

In her sur-reply, claimant argues that she should receive Matrix A benefits because, at the time of her surgery, her regurgitation was characterized as severe and that, prior to Diet Drug use, an echocardiogram noted that the level of her mitral regurgitation was "normal." Claimant further asserts that the Trust did not determine whether her papillary muscle rupture "was related to a condition caused by Diet Drugs."

After reviewing the entire show cause record, we find claimant's arguments are without merit. The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits if he or she is diagnosed with specific medical conditions, including chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation. See Settlement Agreement § IV.B.2.d.(2)(c)ii)c). As claimant's attesting physician concedes, and claimant does not adequately contest, that she has chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation, the Settlement Agreement requires that Ms. Tassinari's claim be reduced to the B Matrix.

Claimant's assertion that her medical records reflect that she does not have chordae tendinae rupture does not alter this conclusion. As an initial matter, Dr. Kemper attested, and Dr. Oliner confirmed, that Ms. Tassinari had chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation. In any

event, the medical records relied upon by claimant do not support her argument. Claimant's Operative Report specifically notes papillary muscle rupture, and claimant's Pathology Report notes papillary muscle rupture as well as acute myocardial infarction (a condition confirmed by the attesting cardiologist). Thus, claimant's attesting physician, and her own medical records, confirm the presence of a medical condition that requires the payment of her Level IV claim on the B Matrix.

Similarly, claimant does not contest the fact that her December 14, 2002 echocardiogram, which was performed between the time of her Diet Drug use and the end of the Screening Program, demonstrated mild mitral regurgitation, another reduction factor. Although claimant asserts that her level of mitral regurgitation progressed from mild to severe, this issue is irrelevant to application of this reduction factor. The Settlement Agreement thus requires that Ms. Tassinari's claim be reduced to the B Matrix due to the presence of this condition as well.

Finally, the court rejects Ms. Tassinari's argument that she is entitled to Matrix A benefits because the ingestion of Diet Drugs caused all of her physical ailments, including the papillary muscle rupture. Causation is not at issue in resolving claims for Matrix Benefits. Rather, claimant is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate
that their injuries were caused by ingestion
of Pondimin and Redux in order to recover

Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we stated:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true, namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the medical condition at issue. The Settlement Agreement unequivocally requires a mitral valve claim to be reduced to Matrix B if papillary muscle rupture is present or if a claimant is diagnosed with mild mitral regurgitation between Diet Drug use and the end of the Screening Period. We must apply the Settlement Agreement as written. Accordingly, claimant's assertion that she did not have any physical ailments prior to Diet Drug use is irrelevant to the issue before the court.¹²

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable

12. We also reject claimant's assertion that the Trust "ignored" the reports of claimant's physicians. As noted above, Ms. Tassinari's own medical reports and the attestations of her physicians reflect that two separate reduction factors are present.

medical basis for her claim for Matrix A-1, Level IV benefits. Therefore, we will affirm the Trust's denial of Ms. Tassinari's claim for Matrix A benefits and the derivative claim submitted by her spouse.